REMARKS

This Reply is being filed in response to the Office Action mailed on October 20, 2006 setting forth a shortened statutory time for response of three months. Accordingly, this Reply is timely filed. Claims 1-12 are pending in this application and stand rejected. Applicants respectfully traverse these rejections.

I. Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 2, 6 and 10 stating these claims fail to comply with the written description requirement because they allegedly "do not identify the structure, material, or acts set forth in the specification that would be capable of carrying out the functional properties recited in the claims." (OA, page 2) Applicants have amended the specification to add the gelling polymers to new paragraph [0017]. This amendment to the specification is supported by claims 3, 7 and 11 as originally filed, and, therefore, this amendment does not add new matter. Applicants submit they have included sufficient structure in the rejected claims by reciting a gelling polymer from 6%-50% of the capsule (claim 1), tablet (claim 5) or sustained release dosage form (claim 9) to achieve the recited sustained release profiles in the rejected claims. Thus, Applicants respectfully request a withdrawal of the rejection of these claims under 35 U.S.C. § 112.

II. Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claim 1-12 under 35 U.S.C. § 103 (a) as being unpatentable over Raffa et al. (U.S. Patent No. 5,336,691) in view of Kaiko et al. (U.S. Patent No. 6,375,957). Applicants respectfully traverse the rejection of these claims.

Raffa et al. discloses a composition of tramadol and acetaminophen for oral administration for treatment of pain and tussive conditions.

Kaiko et al. discloses combining together an opioid agonist, an opioid antagonist and acetaminophen (APAP) in a form suitable for oral administration by a human subject for treatment of pain. Kaiko et al. discloses that "In certain preferred embodiments, the dosage forms provide a sustained release of the opioid agonist, and provide the part or all of the dose of the opioid antagonist in (i) immediate release form, (ii) sustained release form, or (iii) both immediate and sustained release form." (Col. 7, lines 40-45) Kaiko et al. defines "sustained

release" "as the release of the drug (opioid analgesic) from the oral formulation at such a rate the blood (e.g., plasma) concentrations (levels) are maintained within the therapeutic range (above the minimum effective analgesic concentrations or ("MEAC") but below toxic levels over a period of time indicative of twice-a-day formulation." (Col. 8, lines 30-37) Kaiko et al. defines "opioid analgesic" as "...the base of the opioid, mixed agonist-antagonists, partial agonists, pharmaceutical acceptable salts thereof, ethers and esters thereof, and mixtures thereof." (Col. 8, lines 41-46)

Applicants submit the Examiner has failed to state a prima facie case of obviousness as Kaiko et al. alone or in combination fails to teach or disclose a capsule, tablet or dosage form that is suitable for sustained release of both tramadol and APAP. All of the claims require an immediate release portion having both tramadol and APAP and a sustained release portion having both tramadol and APAP. As set forth above, Kaiko et al. discloses sustained release of an opioid analgesic which can include an opioid agonist and an opioid antagonist. Kaiko et al. does not disclose a sustained release formulation where both an opioid analgesic and an APAP are in a form suitable for sustained release of both components. Thus, the combination of Kaiko et al. and Raffa et al. fails to meet every element of the rejected claims and, therefore, the combination does not render the claims obvious. Accordingly, Applicants respectfully request a withdrawal of the rejections under 35 U.S.C. § 103(a).

Additionally, Kaiko et al. discloses in general terms providing a sustained release dosage form or a combination of sustained release and immediate release. Neither Kaiko et al. nor Raffa et al. disclose a capsule, tablet or dosage form having 25%-75% of the drugs in an immediate release form and 25%-75% in a sustained release form. Thus, these limitations also are not met by either reference alone or in combination. For this additional reason, the examiner has failed to present a prima facie case of obviousness, and, therefore, Applicants respectfully request a withdrawal of the rejection of claims 1-12 under 35 U.S.C. § 103(a).

Applicants submit that these amendments place the claims in condition for allowance and request an early notice of the same.

Respectfully submitted,

ROCKEY, DEPKE & LYONS, LLC.

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BY _____

Joseph A. Fuchs, Reg. No. 34,604
233 S. Wacker Drive
Suite 5450, Sears Tower
Chicago, IL 60606
312-277-1132